Medical Coverage Policy | Cranial Electrotherapy Stimulation and Auricular Electrostimulation

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OVERVIEW
Cranial electrotherapy stimulation (CES), also known as cranial electrical stimulation, transcranial electrical stimulation, or electrical stimulation therapy, delivers weak pulses of electrical current to the earlobes, mastoid processes, or scalp with devices. Auricular electrostimulation involves stimulation of acupuncture points on the ear. Cranial electrotherapy stimulation and auricular electrostimulation are being evaluated for a variety of conditions, including pain, insomnia, depression, anxiety, and weight loss.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
BlueCHiP for Medicare and Commercial Products
Cranial electrotherapy stimulation (also known as cranial electrostimulation therapy) is not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

Electrical stimulation of auricular acupuncture points is not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE
Benefits may vary between groups and contracts. Please refer to the appropriate section of the Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for services not medically necessary.

BACKGROUND
Cranial electrotherapy stimulation, also known as cranial electrical stimulation, transcranial electrical stimulation, or electrical stimulation therapy, delivers weak pulses of electrical current to the earlobes, mastoid processes, or scalp with devices such as the Alpha-Stim. Auricular electrostimulation involves stimulation of acupuncture points on the ear. Devices, including the P-Stim and E-pulse, provide ambulatory auricular electrical stimulation over a period of several days. CES and auricular electrostimulation are being evaluated for a variety of conditions, including pain, insomnia, depression, anxiety, and weight loss.

Interest in CES began in the early 1900s on the theory that weak pulses of electrical current have a calming effect on the central nervous system. The technique was further developed in the U.S.S.R. and Eastern Europe in the 1950s as a treatment for anxiety and depression, and use of CES later spread to Western Europe and the United States as a treatment for various psychological and physiological conditions. Presently, the mechanism of action is thought to be the modulation of activity in brain networks by direct action in the hypothalamus, limbic system, and/or the reticular activating system. One device used in the United States is the Alpha-Stim CES, which provides pulsed, low-intensity current via clip electrodes that attach to the earlobes. Other devices place the electrodes on the eyelids, frontal scalp, mastoid processes, or behind the ears. Treatments may be administered once or twice daily for several days to several weeks.

Other devices provide electrical stimulation to auricular acupuncture sites over several days. One device, the P-Stim, is a single-use miniature electrical stimulator for auricular acupuncture points that is worn behind the

ear with a self-adhesive electrode patch. A selection stylus that measures electrical resistance is used to identify 3 auricular acupuncture points. The P-Stim device connects to 3 inserted acupuncture needles with caps and wires. The device is preprogrammed to be on for 180 minutes, then off for 180 minutes. The maximum battery life of this single-use device is 96 hours.

Regulatory Status

A number of devices for cranial electrotherapy stimulation have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. In 1992, the Alpha-Stim® CES device (Electromedical Products International) received marketing clearance for the treatment of anxiety, insomnia, and depression. Several devices for electroacupuncture designed to stimulate auricular acupuncture points have been cleared for marketing through the 510(k) process.

Cranial Electrotherapy Stimulation

For individuals who have acute or chronic pain, or psychiatric, behavioral, or neurologic conditions (e.g., depression and anxiety, Parkinson's disease, schizophrenia, personality disorder, addiction), or functional constipation who receive cranial electrotherapy stimulation, the evidence includes a number of randomized sham-controlled trials, along with several systematic reviews. Relevant outcomes are symptoms, morbid events, functional outcomes, and treatment-related morbidity. There is a lack of consistent evidence for improvement of health outcomes. The largest body of evidence is for depression and anxiety; for that indication, in 2 of 3 sham-controlled trials, no differences were reported in outcomes between groups. The evidence is insufficient to determine the effects of the technology on health outcomes.

Auricular Electrostimulation

For individuals who have acute or chronic pain (e.g., acute pain from surgical procedures, chronic back pain, chronic pain from osteoarthritis or rheumatoid arthritis) or obesity who receive auricular electrostimulation, the evidence includes a limited number of trials from the same research group. Relevant outcomes are symptoms, morbid events, functional outcomes, and treatment-related morbidity. Studies evaluating the effect of this electrostimulation technology on acute pain are inconsistent, and the small amount of evidence on chronic pain has methodologic limitations. For example, a comparison of auricular electrostimulation with manual acupuncture for chronic low back pain did not include a sham-control group, and, in a study of rheumatoid arthritis, auricular electrostimulation was compared with autogenic training and resulted in a small improvement in visual analog scale pain scores of unclear clinical significance. Overall, the few published studies have small sample sizes and methodologic limitations. The evidence is insufficient to determine the effects of the technology on health outcomes. Therefore, these services are considered not medically necessary for BlueCHiP for Medicare and Commercial products.

CODING

BlueCHiP for Medicare and Commercial Products

There is no specific CPT or HCPCS code for Cranial electrotherapy stimulation; therefore providers should report this service with an unlisted procedure code.

The following HCPCS code is not medically necessary:

S8930 Electrical stimulation of auricular acupuncture points; each 15 minutes of personal one-on-one contact with patient

RELATED POLICIES

None

PUBLISHED

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